Attorney Docket No.: 6520.200-US
Application No.: 10/619,237
Filed: July 14, 2003
Title: Medical Delivery Device
Via Facsimile No.: 571-273-8300

REMARKS:

Amendments to claims

New claim 24 corresponds to original claim 19, however, the step "disconnecting the fluid communication between the delivery device and the body of the patient after approximately 7-9 hours" has been replaced by the step "discontinuing delivery of the drug to the patient after approximately 7-9 hours". This amendment is based on page 5, lines 25-29 of the specification wherein it is disclosed that drug delivery can also be stopped either by the expelling means being stopped or due to the reservoir being empty, and thus not merely by disconnecting the fluid communication.

New claim 25 corresponds to original claim 20 with the amendment that the term "infusion device" has been replaced with the term "delivery device" as also used in new claim 24 upon which claim 25 is dependent, this amendment addressing the objection forwarded by the Examiner in respect of original claim 20.

The Examiner has objected to the term "bedtime" in original claim 21, thus, in corresponding new claim 26 the term "at bedtime" has been replaced by the definition "at a time after which the patient is expected to sleep for a period of approximately 7-9 hours", a definition which it is submitted corresponds to the general expectation as to what is expected to happen after "bedtime". Further, in new claim 26 it has been defined that the drug is "being infused substantially corresponding to the period of sleep" (i.e. a period of approximately 7-9 hours), this as described on page 11, lines 18-25 of the specification.

The Examiner has objected to original claim 23 being incomplete for omitting essential features of the delivery device. Original claim 23 was dependent on original claim 1 in which features of the delivery device were defined. Thus, in corresponding new claim 28 the technical features of original claim 1 has been added.

New dependent claim 29 defines that the fluid communication between the delivery device and the body of the patient may be disconnected after approximately 7-9 hours, this as previously defined in the independent claim.

No other amendments have been made to the claims.

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Claim rejections – 35 USC 112

The Examiner has objected to original claims 20, 21 and 23 as not being in compliance with 35 USC 112. In response hereto Applicant has submitted new claims addressing all objections set out, this as explained in detail above.

Claim rejections – 35 USC 102

The examiner has rejected claims 19-23 under 35 USC 102(b) as being anticipated by Gross et al US patent 5,848,991.

Claim 24 defines (step numerals added):

A method for the treatment of a patient suffering from a decease, comprising the steps of:

(a) providing a delivery device adapted to deliver an amount of a drug beneficial for the treatment of the decease,

(b) establishing at a given time a fluid communication between thedelivery device and the body of the patient,

(c) delivering a therapeutic amount of the drug during a period of approximately 7-9 hours, and

(d) discontinuing delivery of the drug to the patient after approximately 7-9 hours.

Gross et al does not explicitly state that a therapeutic amount of the drug should be delivered during a period of approximately 7-9 hours, however, as delivery during 24 hours is disclosed it can be argued that as part of the 24 hours delivery also delivery during 7-9 hours is disclosed and that correspondingly also step (c) is known.

In respect of step (d), i.e. discontinuing delivery of the drug to the patient after approximately 7-9 hours, it appears that the Examiner submits that Gross et al "implicitly" discloses discontinuing (or disconnecting) delivery of the drug after a period of approximately 7-9 hours. However, no such information can be found in Gross et al, neither explicitly nor implicitly. And it does not necessarily follow that Gross requires discontinuing drug delivery after approximately 7-9 hours.

The Examiner has also indicated a number of further prior art references allegedly considered pertinent to applicant's invention, however, corresponding to Gross et all, there appears to be no disclosure of discontinuing delivery of a drug after a period of approximately 7-9 hours.

Non-obviousness – 35 USC 102

The present invention provides a new method and corresponding device which makes a new and safe treatment of diabetes type 2 possible.

As correctly identified by the Examiner, the prior art discloses drug infusion devices which may be set to operate for a given pre-defined period of time, however, these prior art disclosures just mention some examples of drug infusion duration which are not relevant to the present invention. Thus, the present invention can be considered an "election invention" by providing (i) a specific and narrow selection of parameters, and (ii) advantages which are not possible outside the defined range.

(I) Special selection

The prior art cited by the Examiner discloses some examples of drug infusion duration. For example US 5,858,001 discloses infusion of a drug which may be insulin, duration of infusion (for any type of drug) may be e.g. 12h, 24h or 48h. Gross et al merely mentions that the delivery rate can be varied during a 25 hour cycle.

As appears, the present invention defines a narrow range, i.e. 8 (+/-1) hours compared with the above disclosed examples, a range which is intimately related with a specific feature of the human day-cycle, i.e. the 8 hours of sleep, a feature which is neither disclosed nor hinted at in the cited prior art.

(II) Advantages associated with the selected range

As disclosed on page 3 of the present description, the invention is based on the treatment principle that a patient will take an insulin injection (e.g. using NPH insulin) at bedtime and an oral medication during the day (often referred to as combination therapy), this as described by Yki-Järvinen et al., however, this regimen is associated with some problems as also explained.

Correspondingly, it is the stated object of the present invention to provide a concept for the early insulin treatment of diabetes which is acceptable to both the medical practitioner and the patient, which is safe in use and which will overcome the existing prejudices against needle based insulin treatment, see page 5 of the specification.

Thus, in accordance with the invention, a method of using a drug delivery device is described providing a number of advantages to the patient, advantages which were not possible with any known kind of device:

The present invention is based on the concept of drug treatment performed substantially only during the approximately 8 hours during which a patient is at sleep, this being made possible by the method and drug delivery device of the present invention, a method and drug delivery device providing a number of advantages to the patient, advantages which were not possible with any known kind of method or device

From the patients point of view: It is no longer necessary to carefully remember to take the injections (one cannot count the remaining number of tablets as it is possible with oral treatment), but simply to ensure that the method is performed using a drug delivery device as specified.

From the medical practitioners point of view: He/she Will no longer be concerned with the risk of overdosing (e.g. the patient taking too large doses and/or taking too many injections) and thereby the risk for hypoglycemic incidences. This problem is further exaggerated as many patients are middle-aged or elderly and are thus not used to, and perhaps do not understand, the kind of accuracy needed in insulin treatment. With the present invention the patient just has to connect to a delivery device and implement the method.

These advantages are intimately related with the coupling of treatment to the normal sleep cycle of patients and thus the present invention, advantages which could not be realized with a drug delivery device with an operational duration of e.g. 2 or 12 hours as known from the prior art.

Further, neither Gross et al alone nor the cited prior art hint at or fairly suggest to modify a device of the type known from Gross et al in order to solve the problem addressed by the present invention, i.e. in order to solve the problems associated with insulin infusion at bedtime.

Conclusion

In conclusion, Gross et all alone or in view of any of the references on file fails to make obvious to the skilled person a modular system as defined in new claim24.

All further claims are dependent upon an independent claim.

In view of the above, applicants respectfully submit that all claims are in condition for allowance.

The Commissioner is hereby authorized to charge any fees, including fees for extensions of time, in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. Should the Examiner have any questions or concerns, she should feel free to contact the applicants' attorney to discuss them.

Respectfully submitted,

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